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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/718,685

11/21/2000

Eugeni A. Vaisberg

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11/22/2005

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EXAMINER

ZEMAN, MARY K

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 11/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/718,685

Applicant(s)

VAISBERG ET AL.

Examiner

Mary K. Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 40-43 and 51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 40-43 and 51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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**DETAILED ACTION**

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1631, Examiner Mary K Zeman.

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/22/05 has been entered.

The Supplemental amendment, and IDS filed with the RCE request have been entered.

On the IDS form, all cited references have been considered. However, the citations of Office Actions in copending applications are not published documents, and are not appropriate to cite on the face of any issued patent, and have been lined through, as per MPEP 609.

Claims 40-43 and 51 are pending in this application.

***New Grounds of Rejection******Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 40-43 and 51 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 49, 50, 54, 56, 57, 60, 61 and 63-65 of copending Application No. 09/311,996. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims are drawn to computer program products which can perform the same functions, comprising code for capturing, producing, and generating the same types of data.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 40-43 and 51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The examiner has thoroughly reviewed the prosecution history of this application.

Claim 40 recites a computer program product, for a listed intended use, which comprises code for capturing a scalar morphological value derived from 2 components from each cell of a plurality of cells; code for producing a fingerprint characterizing the cells which is a vector; code for producing a profile by comparing the fingerprint to a previously provided database; code for mapping the cells, and a computer readable medium.

The specification, as filed, does not provide written description for a computer program product comprising each of these limitations. The Examiner probed the specification for basis

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for the pending claims. While actual programming code is not required to provide written description for a computer program product, the specification must provide adequate description of the claimed invention, and the steps to be performed by the product. (In re Dossel CAFC 42 USPQ2d 1881) At page 4 of the specification, the computer software for mapping a manipulation of cells comprises code for providing and manipulating the cells, and code for capturing a morphological value. At line 24 it specifies that the program requires an assignment of "a degree of presence of the morphological value" in order to process the statistical analysis to produce a "statistical profile". This is not the same as producing a profile which is a fingerprint which is compared to a known database, and is not a description of the invention as presently claimed. Page 6 of the specification references a trade name of a program "CYTOMETRIX" without enumerating its functions or related codes. Page 7 discloses a generic computer system for use in the disclosed methods. Pages 8-11 list components of cells which may be "captured" however, this part of the specification does not indicate how two components are captured and used to create a fingerprint for each cell, or plurality of cells. Page 11 enumerates manipulations which may be performed prior to capture. This is set forth in the intended use clause of the claim, and does not appear to materially affect the listed code requirements. Pages 12-14 set forth various descriptors which appear to be similar to the claimed "fingerprints" in that vector values can be created. However, how these vectors are to be created is not described. A database is described at page 14 which has one or more "cellular fingerprints" comprised of descriptors. This is not a database comprising the same types of vectors (combinations of descriptors) created by the claimed program, therefore, the "statistically comparing" cannot take place. Comparable data does not appear to be present in the database. Page 16-19 describes Figure 2B and other digital imaging requirements. Image analysis is not required for the claimed computer product. No mapping or graphing of the fingerprints, or statistical profiles is disclosed. Intended use of certain captured values are set forth at pages 19. At page 20, the method/ code for mapping cells specifically is to link a manipulation to a morphological characteristic. That is not the invention under examination. The instant product does not link a morphological characteristic to a particular manipulation. Page 21 discloses an example wherein cell cycle analysis is performed and specific images are captured, analyzed and used to generate a "morphometric value." This is not an example of the claimed product. Pages 21-23 disclose image analysis procedures. These

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are not set forth in the claimed product. Page 24 discloses capturing scalar morphological values. A vector of 2 or more scalar values extracted from cells grown under the same conditions together comprise a unique fingerprint. The data is extracted from fluorescence images. Image analysis is not identified in the claimed product. The cells do not need to be all manipulated or grown under the same conditions. Prophetic disclosure of correlations which "can be made" between fingerprints before and after manipulation is set forth at pages 24-25. How the vectors are to be provided or compared is not set forth. At page 25, various statistical manipulations are stipulated for providing the claimed correlations: phylogenetic trees, statistical classification, neural networks; clustering: none of which are recited in the claimed product. Pages 26-27 further describe a database, and use of the database. These are not inventions under examination. The Experiments section sets forth methods of analyzing cells, but not computer program products comprising the listed code. Pages 35-45 set forth pseudocode for the ANALYSEDNA.m program. This program comprises code for capturing morphological parameters from image files; code for assigning intensity parameters; and outputs a file for each image with values for 14 different measurements. Then, code for creating a summary file is provided. This is not an example of the claimed product. Appendix A and Appendix B are representative outputs for the ANALYSEDNA.m program and do not provide further code/programming information. Therefore, the specification fails to provide written description for the computer program product being claimed.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 40-43, 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pauwels et al. (1997: IDS #50) in view of Paull (1989: IDS #169).

The claims are drawn to a computer program on media that executes a cell analysis method comprising steps of capturing values of components of a plurality of cells that have been manipulated, producing composite descriptors that include information from cells of different types, and use of principal component analysis to produce a fingerprint of the effect of the manipulation on the different cell types. In some embodiments the components of the cells are organelles or nucleic acids, the manipulation is application of a chemical compound such as a drug. Specific cells include MCF-7 cell lines.

Pauwels et al. shows in the abstract and throughout a method of analyzing the effect of a variety of antitumor drugs on tumor cell lines by analysis of digital images of treated cells. Three cell lines and thirty drugs were examined. On page 107, Pauwels et al. details the computer mediated image analysis of the cells. Pauwels et al. determines 15 of parameters of the cells and derive data for the cells including nuclear area, DNA content, and chromatin texture. Pauwels et al. shows in figures 3-6 the results of principal component analysis for the drugs for each cell line. In figure 6 Pauwels et al. show that the analysis shows that classes of drugs with common features and modes of action can be determined by formation of centroids in the analysis. Pauwels et al. concludes on pages 112-114 that their method can be used to assign drugs to classes of drugs on the basis of the effects of the drugs on treated cells as determined by their image analysis method. Pauwels et al. does not show descriptors or fingerprints that comprise information of a plurality of cell lines.

Paull et al. shows a computer program called COMPARE that analyzes the effect of antitumor drugs on a panel of 60 different tumor cell lines. The information obtained from the cell lines was growth inhibition. A specific cell line used by Paull is MCF-7. Paull et al. show on page 1089 that their method produces fingerprints for each drug tested that show a structure-function relationship. Paull et al. Calculates statistical measures of growth inhibition that

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considers the effect of a drug on all cell lines tested in pages 1089-1091, and the data are summarized in Table 2. Paull et al. conclude that drugs with similar modes of action cluster with similar values on page 1092.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to write a computer program to perform the method of Pauwels et al. because Pauwels et al. shows use of algorithms to analyze cell image data and Paull et al. shows a computer program that performs similar analysis of drug treated tumor cell lines. It would have been further obvious to modify the program of Pauwels et al. by construction of descriptors or fingerprints derived from the plurality of tumor cell lines tested by Pauwels et al. because Paull et al. shows that consideration of data from a plurality of tumor cell lines allows for drugs to be clustered by mode of action or structure while considering their effects on a wide range of tumor cell types.

### *Conclusion*

No claim is allowed.

In view of the RCE filing, the and new grounds of rejection this action is NON-FINAL.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (571) 272 0723

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, PhD can be reached on (571) 272 0718. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.


Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the



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MARY K. ZEMAN  
PRIMARY EXAMINER  
A-11631  
11/7/05